

Attachment 5-7 IRB Protocol Review Standards

IRB PROTOCOL REVIEW STANDARDS <u>Minimal regulatory requirements for IRB review, discussion and documentation in the meeting minutes</u>	
<u>Regulatory review requirement</u>	<u>Suggested questions for IRB discussion</u>
1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.	(a) Is the hypothesis clear? Is it clearly stated? (b) Is the study design appropriate to prove the hypothesis? (c) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.	(a) What does the IRB consider the level of risk to be? (See risk assessment guide on back of form.) (b) What does the PI consider the level of risk/discomfort/inconvenience to be? (c) Is there prospect of direct benefit to subjects? (See benefit assessment guide on back of form.)
3. Subject selection is equitable.	(a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers? (b) Are these subjects appropriate for the protocol?
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.	(a) Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired?
5. Informed consent is obtained from research subjects or their legally authorized representative(s).	(a) Does the informed consent document include the eight required elements? (b) Is the consent document understandable to subjects? (c) Who will obtain informed consent (PI, nurse, other?) & in what setting? (d) If appropriate, is there a children's assent? (e) Is the IRB requested to waive or alter any informed consent requirement?
6. Risks to subjects are minimized.	(a) Does the research design minimize risks to subjects? (b) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?
7. Subject privacy & confidentiality are maximized.	(a) Will personally-identifiable research data be protected to the extent possible from access or use? (b) Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?
<u>Additional considerations</u>	
1. Ionizing radiation.	If ionizing radiation is used in this protocol is it medically indicated or for research use only?
2. Collaborative research.	Is this domestic/international collaborative research? If so, are SPAs or other assurances required for the sites involved? Is there a CRADA?
3. FDA-regulated research	Is an IND or IDE involved in this protocol?

Attachment 5-7

Risk/Benefit Assessment

RISK

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).

Check appropriate risk category:

1. ☐ The research involves no more than minimal risk to subjects.
2. ☐ The research involves more than minimal risk to subjects.
☐ The risk(s) represents a minor increase over minimal risk, **or**
☐ The risk(s) represents more than a minor increase over minimal risk.

BENEFIT

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category(ies):

1. ☐ no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (mainly for patient subjects);
2. ☐ no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society's understanding of the disorder or condition under study (mainly for healthy volunteers); or
3. ☐ the research involves the prospect of direct benefit to individual subjects.